REMARKS

Applicants have received and reviewed an Office Action dated October 3, 2003. Applicants request entry of this Amendment and Response and reconsideration of the rejection of the claims.

Applicants cancel claims 2, 5, 6,10, and 13-28 without prejudice or disclaimer. Applicants reserve the right to pursue any subject matter of these claims in a continuation application.

Applicants have amended claims 1,11, and 12. The amended claims are supported throughout the specification including at page 7, lines 3-7; page 15, lines 13-14; page 31, lines 36-37; and page 37, lines 15-18.

With respect to all amendments, Applicants have not dedicated or abandoned any unclaimed subject matter and have not acquiesced to any objection and/or rejection made by the Examiner. Applicants expressly reserve the right to pursue the canceled subject matter in one or more continuation applications.

New claims 29-51 have been added. The newly added claims are supported throughout the specification including at page 19, line 16 to page 20, line 10; page 28, line 10 to page 29, line 21; page 38, line34-37; page 40; page 58, lines 9-37; page 49, lines 30-38; page 43, line 24 to page 44, line 34; and Figure 1. No new matter has been added with the addition of the new claims.

Objection

The Examiner objected to claim 11 as being in improper dependent form. Applicants have amended claim 11 to correct the dependency and request withdrawal of the objection.

35 U.S.C. § 112

The Examiner rejects claims 1-4, 7-9, 11 and 12 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. The

Examiner alleges that the claims encompass a broad genius of fusion proteins that are fused to a major coat protein of the virus. The Examiner states that the scope of these claims includes an infinite number of heterologous polypeptides fused to a major coat protein "wherein no distinguishing structural attributes are provided for the sequence of either the heterologous polypeptide or the major coat protein." The Examiner also indicates that the specification and claims do not place any limit on the number of atoms, the types of atoms, or the manner in which said atoms might be connected to form the sequence of either the polypeptide of the major coat protein. Applicants respectfully traverse this rejection.

As noted in the Guidelines for Examination of Patent Applications Under 35 U.S.C. § 112, ¶1, "Written Description" Requirement ("the guidelines"), there is a "strong presumption" that an adequate written description of the claimed invention is present when the application is filed, 66(4) Fed Reg. 1099, 1105 (2001); see also, In re Wertheim, 191 USPQ 90,97 (CCPA 1976). The guidelines further state that "[(The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims." 66(4) Fed. Reg. at 1107; 191 USPQ at 97, (emphasis added). Compliance with the written description requirement does not require an applicant to describe exactly the subject matter claimed; rather, the description must clearly allow a person of ordinary skill in the art to recognize that he or she invented what is claimed. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). The test is whether the originally filed specification reasonably conveys to a person having ordinary skill in the art that applicant had possession of the subject matter later claimed. In re Kaslow, 217 USPQ 1089 (Fed. Cir. 1991). Moreover, in order to have possession of members of a claimed genus, the specification need not describe all of the species that the genus encompasses. Amgen Inc. v. Chugai Pharmaceutical Co., 18 USPQ2d 1016, 1027 (Fed. Cir. 1991).

Claim 1 recites a fusion protein comprising a heterologous polypeptide fused to a at least a portion of a major coat protein of a virus selected from the group consisting of filamentous phage, a lambda phage, a Baculovirus, a T4 phage and a T7 phage, wherein

the major coat protein is a variant of a wild type major coat protein of a virus.

Applicants submit that an adequate written description of the claimed invention is provided in the specification as filed. Applicants' claims are directed to a fusion protein comprising a heterologous protein fused to at least a portion of a variant of a wild type major coat protein of a virus. Applicants have described and identified many heterologous proteins at page 27, lines 4-30 and page 28, line 10 to page 29, line 31. Any one of these proteins can be combined with the variant coat protein to form a fusion protein useful, for example, in phage display. No common structural feature of the heterologous proteins is required.

In addition, Applicants have described a variety of wild type viral major coat proteins known to those of skill in the art to be useful, for example, in phage display. Applicants have identified some of these wild type proteins structurally by the amino acid sequence as shown on page 40. The amino acid sequences of other wild type viral coat proteins are known. Applicants have described the characteristics of these known viral coat proteins at page 43, line 13 to page 44, line 34. These viral coat proteins share the function of providing for phage display of heterologous proteins. The inventors have discovered that in some embodiments, virus particles that do not have a wild type coat protein can provide for even better phage display. Applicants have also provided several examples of variant viral coat proteins that provide for display of a heterologous protein. Thus, Applicants have described several variant viral coat proteins, both structurally and functionally.

Based on the foregoing, Applicants respectfully request withdrawal of the § 112 rejection on this basis.

The Examiner rejects claim 4 under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. The Examiner alleges that the omitted element is that amino acid residue position 10 is missing and states that the sequence of the major coat protein is incomplete. Applicants respectfully traverse this rejection.

Applicants respectfully direct the Examiner's attention to the wording of claim 4, which recites "the fusion protein of claim 1, wherein the major coat protein is

filamentous phage coat protein variant which contains at least one amino acid residue selected from the list below and the position indicated: . . . . " Thus, applicants point out that the major coat protein described in claim 4 has at least one residue variant at the positions identified in the claim.

For at least these reasons, the Applicants respectfully request withdrawal of the § 112 rejection on this basis.

35 U.S.C. § 102

The Examiner rejects claims 1, 2, 8, 9, 11 and 12 under 35 U.S.C. § 102(b) as being anticipated by Scott et al. Applicants respectfully traverse this rejection.

Independent claim 1 as amended recites a fusion portion comprising a heterologous polypeptide fused to at least a portion of a major coat protein of a virus selected from the group consisting of a filamentous phage, a lambda phage, a Baculovirus, a T4 phage and a T7 phage, wherein the major coat protein is a variant of a wild type major coat protein.

Applicants submit that the Scott et al. reference does not disclose a fusion protein as recited in claim 1. The Scott et al. reference discloses an epitope library which is a mixture of fusion phage "theoretically displaying apparently 4 x 10^7 different hexapeptide epitopes." (p. 386, column 2, 3rd full paragraph). The hexapeptide epitopes are fused to a wild type pIII viral coat protein, a minor viral coat protein. The hexapeptide epitopes are flanked by linkers to minimize the influence of pIII on epitope conformation so the hexapeptide epitope and flanking sequences are a heterologous protein fused to a wild type minor viral coat protein. (p. 387, top lines).

Thus, for at least this reason, Applicants submit that the Scott et al. reference does not anticipate Applicants' claimed invention. Applicants respectfully request withdrawal of the rejection on this basis.

35 U.S.C. § 102(b)

The Examiner rejects claims 1-3, 7, 9, 11 and 12 under 35 U.S.C. § 102(b) as being anticipated by Light II, et al. Applicants respectfully traverse this rejection.

Independent claim 1 as amended recites a fusion protein comprising a heterologous polypeptide fused to at least a portion of a major coat protein of a virus, wherein the major coat protein is a variant of a wild type major coat protein of the virus.

Applicants submit that the Light II et al. reference does not disclose a fusion protein comprising a heterologous polypeptide fused to at least a portion of a major coat protein of a virus, wherein the major coat protein is a variant of a wild type major coat protein of the virus. The Light II reference discloses a matrix comprising a heterologous polypeptide fused to a filamentous phage coat protein anchor *and* a heterodimeric receptor such that one of the dimers is fused to a *second* phage coat protein. The phage coat protein of the Light II et al. reference is the wild type cpVIII of M13. Restriction sites were added to the nucleotide construct, but at a location outside of nucleic acid sequence encoding polypeptide cpVIII. (See col. 55, lines 11-35; compare SEQ ID NO:74 and SEQ ID NO:84).

For at least this reason, Light II, et al. does not anticipate Applicants claimed invention. Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b) rejection.

SUMMARY

Applicants submit that the claims are in condition for allowance and notification to that effect is earnestly solicited. The Examiner is invited to contact Applicants' representative if prosecution may be assisted thereby.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

Date: February 26, 2004

Katherine M. Kowalchyk
Reg. NO:36,848
KMK:sab

23552
PATENT TRADEMARK OFFICE